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THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: George H. SMALL

Confirmation No.: 6750

Application No: 09/972,802

Group Art Unit: 3732

Filing Date: October 9, 2001

Examiner: Pedro Philogene

For: UMBILICAL CORD CLAMP AND
METHODS OF USING SAME

Atty. Docket No.: 104410-100

APPEAL BRIEF FEE TRANSMITTAL

Mail Stop Appeal Brief-Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

The small-entity fee for the Appeal Brief filed on even date herewith is estimated to be **\$250**. No other fees are believed to be due.

Please charge any and all required fees to Winston & Strawn LLP Deposit Account No. 50-1814. A duplicate copy of this sheet is enclosed herewith.

Respectfully submitted,

Date: _____

9/19/06



Jeffrey A. Wolfson

(Reg. No. 42,234)

WINSTON & STRAWN LLP

Customer Number 28765

(202) 282-5770



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Attorney Docket No.: 104410-100

APPEAL BRIEF

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Sir:

Appellant appeals to the Board of Patent Appeals and Interferences (the “Board”) from the decision of the Examiner mailed March 1, 2006, rejecting claims 17-25, 29, and 31-32 and objecting to claim 33.

1. REAL PARTY IN INTEREST

The real party in interest is George H. Small, M.D., M.P.H. ("Dr. Small"), having a residential address of 1415 Cindee Lane, Colton, CA 92324. Dr. Small is the sole owner of the entire right, title, and interest in the invention described and claimed in the above-identified patent application.

2. RELATED APPEALS AND INTERFERENCES

A Notice of Appeal was filed, with provision for the required fee, in this application on February 11, 2005 while awaiting action on the Amendment After Final. In view of the Examiner's refusal to enter the Declaration of Dr. George H. Small, M.D., M.P.H. ("Small Declaration") under 37 C.F.R. § 1.132 along with a few minor claim amendments after final, Dr. Small was left with little choice but to file a Request for Continued Examination instead of pursuing the appeal.

3. STATUS OF CLAIMS

Claims 17-25, 29, and 31-33 are pending. The original Notice of Allowance was mailed on August 6, 2003, and the Issue and Publication Fees were paid for this application on October 20, 2003. Following further intervening prosecution, in relevant part claims 17-25 and 29 were rejected in an Office Action dated July 18, 2005. A responsive Amendment was filed December 12, 2005 adding claims 31-33.

Presently, the rejections are as follows: Claims 29 and 31-33 stand rejected under 35 U.S.C. § 112, second paragraph, for a lack of prior antecedent basis for the term "the depth."¹ Claims 29 and 31-32 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,938,666 to Reynolds et al. ("Reynolds") on pages 2-3 of the Office Action. Claims 17-25 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,006,830 to Merritt ("Merritt") in view of U.S. Patent No. 6,132,447 to Dorsey ("Dorsey") on pages 3-4 of the Office Action.

Claims 17-25 and 29 have been twice rejected in their current form, although dependent claims 31-33 have only been once rejected. The claims appealed, claims 17-25, 29, and 31-32, are presented in Appendix A. Claim 33 is not appealed as it is currently allowable but objected to for being dependent on a rejected base claim.²

4. STATUS OF AMENDMENTS

No claim amendments were filed in response to the final Office Action mailed March 1, 2006.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention generally relates to umbilical cord clamps. In one aspect, the clamp includes a gender-identifying color to facilitate identity recognition. According to convention, the clamps can be any shade of blue color for boys and pink color for girls. Appropriate color pigments can be added to the plastic material before the clamps are molded during the manufacturing process, or they can be painted after manufacture. A portion of the clamp can include the gender-identifying color while the rest of the clamp is a neutral beige or

¹ Appellant agrees to correct this informality upon allowance of this claim, *e.g.*, by adding –having a depth— after "a channel" in claim 29, or alternatively, consents to an Examiner's Amendment to this effect.

white, for example. The neutrally colored part can include a numerical, bar code, or other identifier to further identify other crucial features regarding each newborn. Preferably, the entire clamp is blue or pink to facilitate gender identification. Indeed, a colored clamp can be identified across a room, such that family members, nurses, or the like can easily use the proper pronoun when referring to the newborn to avoid offending the parents or other overly sensitive relatives. Since a clamp is typically placed on most newborns, using a gender-identifying color on the clamp will advantageously avoid the need to resort to various other less-suitable gender-identifying measures. For example, neonatal units often use gender-colored clothing, such as onesies or caps, to identify gender, but mistakes tend to occur when determining gender while the newborn is wearing a diaper or other covering clothes, or when the cap falls off. The likelihood of error in identifying gender is significantly reduced when the newborn first arrives in the "au natural" state. Thus, the doctor, nurse, midwife, or other birthing assistant can apply the properly colored clamp of the invention to the umbilical cord before or immediately after it is cut to facilitate subsequent gender identification for as long as it takes the cord stump to fall off.

The subject matter that is presently rejected includes claims 17-25, 29, and 31-33 is supported as follows. Independent claim 17 recites an umbilical cord clamp **10** including a pair of arms **11, 12** each having a length in a generally V-shaped configuration having rear end portions joined together at the apex thereof (*e.g.*, **13**) and having free forward end portions normally disposed in spaced-apart relation and being movable towards each other to clamp an umbilical cord between the arms **11, 12**, identification means comprising a gender-identifying color associated with a portion of the clamp that is adapted and configured to facilitate identification of the gender of a baby while the clamp remains on the baby, and a locking portion **18, 19** for securing the arms **11, 12** together when the clamp **10** is closed on the baby's umbilical cord (*See, e.g.*, FIG. 1 and Application at page 5, line 21 to page 8, line 17 and page 10, lines 7-28).

Dependent claim 18 recites that the gender-identifying color includes blue to designate a boy and pink to designate a girl (*See, e.g.*, Application at page 10, lines 8-9). Dependent claim 19 recites that the entire clamp includes one or more shades of the color selected (*See, e.g.*, Application at page 10, line 9). Dependent claim 20 recites that the color is visibly imbued within or painted upon the clamp (*See, e.g.*, Application at page 10, lines 9-12).

² Claim 33 has not been rewritten in independent form yet pending this appeal.

Dependent claim 21 recites the identification means further comprises an alpha-numeric indicia, security apparatus, or a bar code to inhibit or prevent unauthorized removal of the baby from a pre-defined area (*See, e.g.*, Application at page 10, lines 14-16 and page 11, lines 3-15).

Dependent claim 22 recites that a portion of the clamp is blue and the remainder is a neutral color for a boy or a portion of the clamp is pink and the remainder is a neutral color for a girl (*See, e.g.*, Application at page 10, lines 8-9 and lines 12-14).³

Dependent claim 23 recites a method of identifying the gender of a newborn baby by applying the clamp of the invention, and visually analyzing the identification means to determine the gender of the baby (*See, e.g.*, Application at page 10, lines 25-28 and 17-22).

Dependent claim 24 recites a method of further identifying a newborn baby by applying the clamp of the invention, and analyzing the identification means to determine the mother of the newborn so as to minimize the chance of misidentification of the baby or the mother thereof (*See, e.g.*, original claim 24 and Application at page 11, lines 3-5). Dependent claim 25 recites a method of inhibiting or preventing unauthorized removal of a newborn baby from a pre-defined area which comprises applying the clamp of the invention, analyzing the identification means to determine at least the date and time of birth of the baby, and permitting only an authorized person to remove the baby from the pre-defined area (*See, e.g.*, Application at page 11, lines 5-7).

In another aspect of the invention, the umbilical cord clamp includes a channel 30 having a depth that extends substantially along the length of at least one arm of the clamp, and is open at the free end portion thereof, to facilitate the escape of fluid therefrom when the clamp is closed, where the depth of the channel increases toward each open end. This advantageously facilitates the flow of fluid out of and away from the clamp. Sufficient removal of fluid helps minimize or avoid infections in or around the clamped vessel, which can occur when pathogen-containing fluid is left in the region around or in the vessel. As might be expected, infections are a particular concern in newborns due to their immature immune systems that cannot cope with certain overwhelming infections.

Independent claim 29 recites an umbilical cord clamp 10 that includes a pair of arms 11, 12 each having a length in a generally V-shaped configuration having rear end portions

³ Appellant also proposes to amend claim 22 at the next opportunity to recite —or— in lieu of "and" to more clearly and distinctly recite the invention.

(e.g., 13) joined together at the apex thereof and having free forward end portions normally disposed in spaced-apart relation and being movable towards each other for clamping an umbilical cord between the arms 11, 12, a channel 30 having a depth that extends substantially along the length of at least one arm and is open at the free end portion thereof to facilitate the escape of fluid therefrom when the clamp is closed and wherein the depth of the channel increases toward each open end, and a locking portion 18, 19 for securing the arms together when the clamp 10 is closed (*See, e.g.*, FIGS. 1-2, Application at page 5, line 21 to page 8, line 17 and page 9, line 5 to page 10, line 6).

Dependent claim 31 recites that the channel has a width of about 1/4 to 1/2 of a width of each arm (*See, e.g.*, Application at page 9, line 22). Dependent claim 32 recites that the channel is present in each arm (*See, e.g.*, Application at page 9, lines 12 to 14). Dependent claim 33 recites that each channel is open only at the free end portion of the arm (*See, e.g.*, Application at page 9, lines 11-12).

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection for appellate review are as follows:

(A) Claims 29 and 31-32 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,938,666 to Reynolds on pages 2-3 of the Office Action; and

(B) Claims 17-25 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,006,830 to Merritt in view of U.S. Patent No. 6,132,447 to Dorsey on pages 3-4 of the Office Action.

7. ARGUMENT

The Examiner's rejections of the pending claims are in error because the product of the invention is neither disclosed nor suggested in the disclosure of any of the above-mentioned references, or any combination thereof, and the present claims are therefore not rendered anticipated or obvious by these references.

With respect to the rejection under 35 U.S.C. § 102(b) of claims 29 and 31-32, Reynolds fails to disclose each and every claimed feature of independent claim 29.

With respect to the rejection under 35 U.S.C. § 103(a) of claims 17-25, the Examiner failed to establish a proper basis for the obviousness rejection because there is: (1) no

motivation to combine the references, and (2) no suggestion of the claimed invention. To establish an obviousness rejection, there must be a showing that there is a motivation to combine the prior art, and that the combination of the prior art teaches or suggests each and every element of the claimed invention.⁴ Lack of a motivation or suggestion demonstrates the patentability of the claims over the cited references.⁵ Without such motivation or suggestion, the rejection is improper and should be withdrawn for that reason alone.

For the reasons below, Appellant respectfully requests that the Examiner's anticipation and obviousness rejections be reversed and that claims 15-25, 29, and 31-32 be allowed.

A. The Novel Channel Arrangement is Not Disclosed by Reynolds

Claims 29 and 31-32 were improperly rejected under 35 U.S.C. § 102(b) over Reynolds on pages 2-3 of the Office Action, which states that Reynolds identically discloses each and every feature recited by these claims. In particular, the Office Action alleges that Reynolds discloses a channel (21,22) with a depth that increases toward each open end as best seen in FIG. 1 (the incline of channel 22 being alleged to increase the depth toward the open end).

On the contrary, Reynolds fails to disclose or even suggest this feature. Reynolds does not even acknowledge that it would be desirable to increase the channel in one direction or the other. Further, Reynolds not only fails to disclose that the channel depth increases toward the open ends of the clamp arms, but it *teaches away* from the claimed invention by disclosing that the webs (21,22) are *parallel to and preferably co-planar* to the root plane of opposite interior serrated surfaces, so blood is forced out of the vessels and artery of the cord in *opposite directions* (Col. 4, lines 38-42). This teaches that blood is removed out either end of the clamp

⁴ *In re Lee*, 277 F.3d 1338 (determining that the Board of Patent Appeals and Interferences improperly relied upon common knowledge and common sense of person of ordinary skill in art to find the invention obvious over combination of two prior art references, since factual question of motivation to select and combine references could not be resolved on subjective belief and unknown authority); *In re Bond*, 910 F.3d 831 (Fed. Cir. 1990) (finding a claimed invention not obvious when the teachings of the two prior art references provided no teaching, suggestion or incentive supporting the combination); *Elf Atochem North America, Inc. v. LaRoche Indus.*, 85 F. Supp.2d 336, 343 (D. Del. 2000) ("Two or more prior art references may be combined to demonstrate obviousness, but the prior art must provide a suggestion or motivation to combine the references"); *see generally*, Chisum, D. *et al.*, Principles of Patent Law, Foundation Press, 1998, pages 530-728.

⁵ *In re Lee*, 277 F.3d at 1338.

arms. Claim 29, however, recites a structure where the net blood flow will occur only in one direction—towards the direction of the open end where the channel depth is increased. Indeed, claim 29 recites that the depth of the channel increases toward each open end, which open ends are disposed at the free end portion thereof to facilitate the escape of fluid therefrom when the clamp is closed. Despite the bald assertion in the Office Action that Reynolds anticipates because its channels increase depth as recited by the claims, it is abundantly clear from the Reynolds disclosure, not to mention FIG. 4 disclosing webs 21,22 that are parallel, that the channel depth is unmodified along its length. Thus, Reynolds fails to teach each and every recited feature of claim 29. Further, Reynolds teaches away from having a sloped channel depth by requiring channel bottoms that are parallel and preferably co-planar to the opposing root plane. Thus, the rejection of claims 29 and 31-32 under 35 U.S.C. § 102(b) should be reconsidered and reversed.

B. The Gender-Identifying Color Is Not Suggested by the Cited References

Claims 17-25 were improperly rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,006,830 to Merritt in view of U.S. Patent No. 6,132,447 to Dorsey on pages 3-4 of the Office Action. Although claims 17-25 were previously allowed and ready for issuance even in view of Merritt, the new rejection imposed and maintained since that time relies on a combination of Dorsey with the previously considered Merritt. Merritt is stated by the Office Action to teach all limitations except an identification means comprising a gender-identifying color to facilitate identification of a baby's gender. To remedy this massive deficiency, the Office Action relies on Dorsey to show "umbilical devices" with gender-identifying color coding.

On the contrary, this exhibits a substantial lack of understanding of the invention—not to mention relying on an improper hindsight rejection. Dorsey is directed to a completely different article—blue or pink labeled scissors used to cut an umbilical cord, rather than an actual umbilical cord clamp that seals the remaining portion of the baby's cord.

By way of background, Merritt discloses an umbilical cord clamp that contains particular types of *unique* identification marks including a serial code, bar code, color code, or letter combination, each of which has a different *distinctive* mark thereon (Col. 4, lines 10-24). Thus, Merritt's purpose is to provide a different identifier mark for every single baby so each can

be distinguished. Merritt fails to disclose the inclusion of a color, including shades thereof, to provide identification means comprising a gender-identifying color to facilitate identification of the gender of a baby, as presently recited. At best, Merritt discloses a distinctive *color code* to prevent unauthorized removal of a newborn from a pre-defined area. Thus, Merritt might be argued to require a unique color code on every clamp, which is presumably at least a pattern of multiple colors, *e.g.*, a multi-colored bar code, to provide identification for its stated purpose of preventing unauthorized removal of a baby from a security zone (*See, e.g.*, Merritt at Col. 2, lines 30-68; and Small Declaration at ¶ 6).

Dorsey, however, is directed to a pair of scissors, as noted above, that are blue or pink labeled and used to cut an umbilical cord. Thus, Dorsey's scissors are merely a novelty item that is packaged for delivery into the parent's hands, or perhaps used once, cleaned, and then packaged. Dorsey's scissors do not remain with the newborn or in association with the umbilical cord, but instead are separately packaged and provided in a nice display for the relatives of the newborn (Dorsey, FIGS. 2-3). At best, Dorsey provides a novelty toy to new parents, or perhaps a souvenir of the baby's birth in the hospital (*See, e.g.*, Small Declaration at ¶ 7). Dorsey does not, however, teach to provide a gender-identifying means including a gender-identifying color that is clamped onto the newborn's umbilical cord or otherwise associated with a portion of the clamp to facilitate identification of the gender of the baby. While Dorsey is simply a reminder to anyone seeing its novelty scissors that the possessor has a *child* of a particular gender, that reminder is **not** attached to the child as is the presently recited clamp. Claim 17 recites that the gender-identifying means facilitates identification of the gender of a baby while the clamp remains on the baby, *i.e.*, the gender-identifying means remains with the baby until the umbilical cord stump and/or clamp fall off or are physically removed. This natural falling off of the cord with clamp on it typically takes 2 to 4 weeks for a typical baby, which is significantly and surprisingly longer than the scissors of Dorsey. In fact, at best, Dorsey teaches momentary contact while the cord is cut but this does not provide gender-identification assistance over time. Dorsey's colored scissors are never on the baby, as presently recited, as they are at most momentarily used to cut the umbilical cord (*See, e.g.*, Dorsey at Col. 3, lines 7-8; and Small Declaration at ¶ 7).

Aside from a hindsight rejection, it is not seen that the cited references themselves provide sufficient motivation that one of ordinary skill in the art would have combined them,

much less arrived at the claimed article and methods. Merritt discloses an unique identification system to deter the unauthorized removal of a newborn from a defined area, while Dorsey provides blue or pink novelty scissors to cut a baby's umbilical cord. Aside from both generally relating to the birthing experience, the references themselves contain absolutely no motivation whatsoever to suggest to one of ordinary skill in the art that they could have been combined in some way (*See, e.g.*, Small Declaration at ¶¶ 8 and 12). In fact, in the ordinary course of usage, those of ordinary skill would apparently have been inclined to use the scissors, remove them for cleaning and packaging, and separately apply (either before or after) the unique identifier clamp of Merritt, and never have combined the clamp and scissors of Merritt and Dorsey.

It is settled law that bald assertion is not sufficient to maintain this rejection, as the Federal Circuit requires that a teaching or motivation to combine be present in the cited art of record. In the obviousness context, a motivation must have existed for one of ordinary skill in the art to combine the references—and this lack of such a motivation in the art of record demonstrates the patentability of the claims over the cited references, or at the very least demonstrates the lack of a *prima facie* case of obviousness by the Patent Office. Absent the motivation to combine a gender-identifying color on a pair of novelty scissors, with a cutting function, with a unique identifier (which might include a color code) for security purposes on an umbilical cord clamp, Merritt and Dorsey simply failed to provide those of ordinary skill in the art with any motivation to apply the gender-identifying color of Dorsey in hindsight and apply it to the uniquely coded article of Merritt (*See, e.g.*, Small Declaration at ¶¶ 8 and 12).

Furthermore, the final Office Action states that Merritt teaches a clamp that remains on the baby, *i.e.*, on the cord stump, and Appellant readily acknowledges this. Dorsey and Merritt, however, still fail to provide a motivation to for one of ordinary skill in the art to provide a gender-identifying color from removable, one-time use scissors onto a different article to provide a gender-identifying function by remaining with the baby for a period of time (*See, e.g.*, Small Declaration at ¶¶ 7-8). Indeed, both cited references fail to even recognize the problem of misidentification of gender that the present invention so elegantly achieves.

Dorsey's separate scissors, with a cutting function, simply do not provide a motivation to keep the presently recited gender-identifying color with the baby, or even to use its colors to identify the gender of the baby on the spot, as Dorsey teaches to place the scissors in a separate frame or package immediately after cutting the cord (*Id.*). No doubt the frame remains

with the parents, as such a sharp-cornered, dangerous object like a frame could not safely remain near the newborn. Additionally, Merritt already teaches a unique coding system, thus obviating the need to provide an additional color coding system to identify the gender of the newborn.

In addition to the lack of motivation to combine within the cited references, Dorsey actually *teaches away* from Merritt, because Merritt discloses that every clamp should have a different distinctive identification mark thereon. Dorsey, however, teaches use of the pink and blue coatings on its scissors to identify gender (Col. 2, lines 13-27) of an entire class of people rather than providing a unique security identifier. Dorsey thus teaches a gender-identifying color on a pair of scissors that is not attached to or on a baby, and that is not a sufficient universe of colors to create a *unique* security code, *e.g.*, a "color code," or to uniquely and distinctly identify every newborn in a given hospital or health care facility, as required by the fundamental purpose of Merritt's teachings (*See, e.g.*, Small Declaration at ¶¶ 6-8). While Dorsey does teach other colors like green and yellow, which are used when the baby's gender is undetermined, those are used in lieu of pink or blue when the gender is unknown. Thus, Dorsey simply does not provide the missing motivation to combine the references and Dorsey and Merritt teach away from combination of their respective inventions.

Moreover, as noted above, Dorsey teaches that the scissors are *separated from the baby* to be cleaned after severing the umbilical cord from the mother, further processed (labeled with birth data), framed or packaged, and presented to the child's parents (*See, e.g.*, FIG. 3 and Small Declaration at ¶ 8). On the contrary, it is essential for Merritt's clamp to *remain on the baby* to provide its inventive security function. Merritt's clamp, to function as intended, is processed before application to the baby for maximum security, while Dorsey's scissors are packaged after cutting and must not remain with the baby. Indeed, Dorsey's scissors are not intended to function as a gender-identifying means, because they are *provided to the child's parents* rather than remaining on or even necessarily near the baby (*See, e.g.*, Small Declaration at ¶ 7). This aspect of Dorsey further teaches away from placing the scissors on a baby, as taught for the clamp of Merritt. In view of these significantly different purposes and functions, one of ordinary skill in the art would clearly not have been motivated to combine selected features from Dorsey and Merritt in the absence of guidance from the present specification regarding the presently recited surprising and unexpected invention (*See, e.g.*, Small Declaration at ¶¶ 8 and 12).

Indeed, the rejection appears to have been made using hindsight, which relies on the Appellant's own filings during prosecution and which is impermissible under the law.⁶ In fact, the Federal Court of Appeals for the Federal Circuit has noted that hindsight must be guarded against, particularly in mechanical inventions, where there is a tendency to pick and choose sections from references to support an obviousness rejection while ignoring the totality of the teachings.⁷ The selection of references appears arbitrary, as the references have no unifying motivation, aside from simply being related to the general idea of obstetrics, for one of ordinary skill in the art to have combined them *at the time of the invention*.

Additionally, dependent claim 21 recites that the identification means further includes an alpha-numeric indicia, security apparatus, or a bar code to inhibit or prevent unauthorized removal of the baby from a pre-defined area. While claim 21 recites a type of identifier like that of Merritt, it clearly distinguishes the gender-identifying color of parent claim 17 from this identification means.

Further, dependent claim 23 recites a method of identifying the gender of a newborn baby by applying the clamp of the invention, and visually analyzing the identification means to determine the gender of the baby. Nothing in Merritt and Dorsey, even if improperly combined, discloses or suggests analyzing the gender-identifying color on the clamp to determine the gender of the baby. Merritt is simply directed to preventing unauthorized removal of a baby from a pre-defined area, while Dorsey teaches a novelty scissors retained separately from the baby with the parents or other relatives. Thus, even combined there is no teaching to use the gender-identifying color to identify the baby's gender.

Additionally, dependent claim 24 recites a method of identifying a newborn baby by applying the clamp including an alpha-numeric indicia, security apparatus, or a bar code, and analyzing the identification means to determine the mother of the newborn so as to minimize the chance of misidentification of the baby or the mother thereof. The references do not disclose correlating and identifying the mother from a gender-identifying color clamp that also includes such an alpha-numeric indicia, security apparatus, or a bar code.

⁶ *Texas Instruments v. United States ITC*, 988 F.2d 1165, 1178 (Fed. Cir. 1998) (it is impermissible to piece the invention together using another patented invention as a template).

⁷ *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 665 (Fed. Cir. 2000) (explaining that the temptation to engage in impermissible hindsight is especially strong with seemingly simple mechanical inventions).

Based on the teachings in the above-identified cited references, one of ordinary skill in the art would not have been motivated to apply the gender-identifying color of Dorsey's scissors onto a clamp that already contained a unique color code or other unique identifier. Accordingly, Dorsey and Merritt, even if combined, simply do not teach or suggest the claimed gender-identifying color of the umbilical clamp presently recited and no motivation existed to pick and choose features of the cited references to achieve the invention recited in claims 17-25. Thus, claims 17-25 are clearly patentable and Appellant respectfully requests that the obviousness rejection be reversed and withdrawn.

C. Evidence of Secondary Considerations – Long-Felt Need

The Examiner rejected at least claims 17-25 without giving due consideration to the evidence presented. Even if a motivation to combine Dorsey and Merritt existed, which it does not, evidence of the secondary factors of obviousness need to be considered in an obviousness determination. One important secondary factor to be considered here is the existence of a long-felt, but unsolved need, in the art for the claimed clamps and methods (*See, e.g.,* Small Declaration at ¶¶ 9-12). The U.S. Supreme Court has established that secondary considerations of nonobviousness must be considered during the examination of claims.⁸ These secondary considerations "must be considered in every case in which they are present[, and when] evidence of any of these secondary considerations is submitted, the Examiner must evaluate the evidence" if the obviousness question is in doubt.⁹ The ultimate determination of patentability is thus made on the entire record.

The Declaration of Dr. Small that was submitted and entered with the Request for Continued Examination on February 11, 2003 included evidence of long-felt need for the present

⁸ *See, Graham*, 383 U.S. 1 (1966); *See also, Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983) (stating that it is jurisprudentially inappropriate to disregard any relevant evidence on any issue in any case, patent cases included. Thus evidence rising out of the so-called "secondary considerations" must always when present be considered en route to a determination of obviousness); *In re Huang*, 100 F.3d 135 (Fed. Cir. 1996) (including evidence of commercial success, long-felt but unsolved needs, failure of others, and copying as secondary considerations); *Ashland Oil v. Delta Resins & Refractories*, 776 F.2d 218, 306 ("all relevant evidence going to the issue of obviousness/nonobviousness, which includes properly presented evidence on secondary considerations, must have been considered prior to reaching a conclusion on obviousness/nonobviousness").

⁹ *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1026 (Fed. Cir. 1985) (overruled on other grounds) (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d at 1539) (opining that secondary considerations are "to be taken into account always, 'not just when the decisionmaker remains in doubt after reviewing the art'").

invention recited in claims 17-25.¹⁰ The Office Action mailed June 23, 2005 completely omitted consideration of the Small Declaration. Pursuant to a telephonic request, Appellant's representative requested that acknowledgement and consideration be given to the Small Declaration showing long-felt need for the claimed invention as set forth in MPEP § 716.04. In a replacement Office Action mailed July 18, 2005, the Small Declaration was found unpersuasive in a paragraph on page 4. Thus, the rejection of claims 17-25 was maintained despite having been previously allowed and ready for issuance.

The Small Declaration sets forth the facts showing the long-standing, but unsolved, need in the art for a superior solution to gender-identification of infants that the claimed articles and methods provide (*See, e.g.*, Small Declaration at ¶¶ 9-12). Umbilical cord clamps have been used to assist in delivery of newborns for decades, at least in various developed countries. The basic model clamp has been in use for much of that time without significant changes. A significant problem in the art is the failure of a reliable method for visitors to the newborn, as well as the parents and hospital staff, to rapidly, accurately, and repeatedly, identify the gender of babies without removing their diaper, *e.g.*, so the proper pronoun can be used (*See, e.g.*, Small Declaration at ¶¶ 9 and 12).

This problem is well known in post-natal wards, and to-date one of the best solutions of others in the art has involved use of blue or pink baby hats or other clothing. Unfortunately, these tend to fall off of babies or be covered by other clothing to keep the newborns and infants warm, and also tend to be applied improperly sometimes when overly tired health care workers re-apply the hat or other colored clothing to a baby after various treatments or inspections. Thus, not only do such hats or clothing not always remain with the child, but the wrong color may be applied to the child at various times causing temporary confusion (*See, e.g.*, Small Declaration at ¶ 9).

The long-felt need has not yet been satisfied to the knowledge of the Appellant, Dr. Small, who began delivering children more than 25 years ago (*See, e.g.*, Small Declaration at ¶¶ 3, 10, and 12). Indeed, as far as Appellant knows, the invention of Dorsey, or the combination of Merritt and Dorsey, has not been adopted by anyone else in the field of art (*Id.*). Thus, the long-felt need still requires a solution, which has been elegantly and cleverly achieved

¹⁰ The Small Declaration.

by the surprising and unexpected invention presently recited in claims 17-25 (*See, e.g.*, Small Declaration at ¶¶ 10-11).

The surprising and unexpected advantages of the claimed invention relative to conventional gender identification (*See, e.g.*, Specification at page 10, lines 17-28 and discussed above) are clear. The present invention elegantly solves the long-standing gender-identification difficulties by applying a gender-identifying clamp to a nude newborn at birth--when the chance for gender misidentification is significantly lower than later times when clothes are worn (*See, e.g.*, Small Declaration at ¶ 11-12). The clamp of the invention does not typically fall off, either, and remains with the diapered-newborn baby until the cord falls off, which is generally after the baby departs from the hospital or other pre-defined area (*See, e.g.*, Small Declaration at ¶ 11). The simple fact is that millions of babies are delivered annually in this country alone, and to the Appellant's knowledge no one has ever achieved such a simple, elegant solution to the problem of gender misidentification of newborn babies (*See, e.g.*, Small Declaration at ¶ 10-12). In fact, it should be clear common sense (in hindsight) that there is a long-felt need in the obstetric art for the improved gender-identifying clamp provided by the claimed invention. For these and other reasons, the rejection under 35 U.S.C. § 103(a) has been overcome and should be reconsidered and reversed, particularly since no *prima facie* case of obviousness has been stated on the record when considering the totality of the evidence in view of the combination of cited references.

The Examiner found this evidence unpersuasive because paragraph 11 was stated to show no long-felt need, in that there was no showing that others in the art were working on the problem and for how long. The problem here was and is clearly recognized by those of ordinary skill in the art, as well as laypersons such as the parents of the newborns. It is persistent and constant—thousands of newborns arrive daily. As to proving that others were "working on the problem," however, this does not appear to be the test set forth by MPEP § 716.04. Nor is it likely that others in the art would publicly declare their efforts to solve the problem, or any partial solutions achieved, prior to achieving success for fear that the idea would be taken without recompense.

Additionally, the Examiner appears to have only considered paragraph 11 of the Small Declaration. The Small Declaration at paragraph 9, however, sets out the long-standing problem recognized by others in the field. Paragraph 10 further highlights that efforts by others

were unsuccessful and not adopted in the art, and that no optimal solution exists even today. Thus, those of ordinary skill in the art were aware of the problem yet were unable to solve it. Thus, the Office Action does not appear to have properly considered the evidence as a whole in connection with the lack of a *prima facie* case of obviousness.

The long-felt need for this umbilical clamp product, and the associated methods, provides significant evidence of secondary considerations related to the non-obviousness of the present invention, and the full weight of this evidence supports the patentability of at least claims 17-25 of the present invention.


8. CONCLUSION

Appellant requests that the rejections of (i) claims 17-25 and of (ii) claims 29 and 31-32, be reversed and that these claims be allowed.

Respectfully submitted,

Date: _____

9/19/06


Jeffrey A. Wolfson (Reg. No. 42,234)

WINSTON & STRAWN LLP
Customer Number 28765

(202) 282-5770

Appendix A -- Claims Appendix

The claims on appeal are:

17. An umbilical cord clamp comprising:
a pair of arms each having a length in a generally V-shaped configuration having rear end portions joined together at the apex thereof and having free forward end portions normally disposed in spaced-apart relation and being movable towards each other to clamp an umbilical cord between the arms;
identification means comprising a gender-identifying color associated with a portion of the clamp that is adapted and configured to facilitate identification of the gender of a baby while the clamp remains on the baby; and
a locking portion for securing the arms together when the clamp is closed on the baby's umbilical cord.
18. The clamp of claim 17, wherein the gender-identifying color includes blue for a boy and pink for a girl.
19. The clamp of claim 17, wherein the entire clamp comprises one or more shades of the color.
20. The clamp of claim 17, wherein the color is visibly imbued within or painted upon the clamp.
21. The clamp of claim 17, wherein the identification means further comprises an alpha-numeric indicia, security apparatus, or a bar code to inhibit or prevent unauthorized removal of the baby from a pre-defined area.
22. The clamp of claim 18, wherein a portion of the clamp is blue and the remainder is a neutral color for a boy and a portion of the clamp is pink and the remainder is a neutral color for a girl.

23. A method of identifying the gender of a newborn baby which comprises applying the clamp of claim 17 and visually analyzing the identification means to determine the gender of the baby.

24. A method of identifying a newborn baby which comprises applying the clamp of claim 21; and analyzing the identification means to determine the mother of the newborn so as to minimize the chance of misidentification of the baby or the mother thereof.

25. A method of inhibiting or preventing unauthorized removal of a newborn baby from a pre-defined area which comprises applying the clamp of claim 21; analyzing the identification means to determine at least the date and time of birth of the baby; and permitting only an authorized person to remove the baby from the pre-defined area.

29. An umbilical cord clamp comprising:

a pair of arms each having a length in a generally V-shaped configuration having rear end portions joined together at the apex thereof and having free forward end portions normally disposed in spaced-apart relation and being movable towards each other for clamping an umbilical cord between the arms;

a channel that extends substantially along the length of at least one arm and is open at the free end portion thereof to facilitate the escape of fluid therefrom when the clamp is closed and wherein the depth of the channel increases toward each open end; and

a locking portion for securing the arms together when the clamp is closed.

31. The clamp of claim 29, wherein the channel has a width of about 1/4 to 1/2 of a width of each arm.

32. The clamp of claim 29, wherein a channel is present in each arm.

Appendix B -- Evidence Appendix

1. The Declaration of George H. Small, M.D., M.P.H. ("Small Declaration")
 - Signed on February 10, 2005; filed on February 11, 2005
 - By George H. Small, M.D., M.P.H.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	G. SMALL	Confirmation No.:	6750
Application No.:	09/972,802	Group Art Unit:	3732
Filing Date:	October 9, 2001	Examiner:	Pedro Philogene
For:	UMBILICAL CORD CLAMP AND METHODS OF USING SAME	Attorney Docket No.:	104410-100

DECLARATION OF GEORGE H. SMALL, M.D., M.P.H. UNDER 37 C.F.R. § 1.132

**Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

Sir,

I, George H. Small, do declare that:

1. I am a United States citizen and currently reside at 1415 Cindee Lane, Colton, California 92324.
2. I received a Bachelor of Arts in Biology and a minor in Chemistry from Atlantic Union College in South Lancaster, Massachusetts in 1965. I received my M.D. from Temple University in 1974, and completed my residency in 1977. Then, I obtained a Masters in Public Health (M.P.H.) degree in Maternal and Child Health and Family Planning from Berkeley in 1978.
3. I have been practicing as a clinical OB/GYN for over 25 years. My employment history includes working as a clinical OB/GYN at the Inland Obstetrics and Gynecology Medical Group from 1980-1998; as clinical OB/GYN and Medical Director at the Loma Linda Community and Medical Group from 1995-1999; as clinical OB/GYN at the Metropolitan Medical Clinic from 1999-2003; and as a clinical OB/GYN and Medical Director of Palo Verde Medical Associates in Blythe, California from December 2004 to the present; with a brief sabbatical during part of 2003-2004.

4. I have reviewed and understand the above-identified patent application, the pending claims, the Office Action, and the references cited by the Examiner in the above-identified application. Specifically, these references are U.S. Patent No. 5,006,830 to Merritt ("Merritt") and U.S. Patent No. 6,132,447 to Dorsey ("Dorsey"). I am making the following statements as one of ordinary skill in the art in support of the patentability of claims 17-25 in this application.

5. Claims 17-25 of the above-identified application are directed to an umbilical cord clamp that includes a pair of arms each having a length in a generally V-shaped configuration having rear end portions joined together at the apex thereof and having free forward end portions normally disposed in spaced-apart relation and being movable towards each other to clamp an umbilical cord between the arms, identification means comprising a gender-identifying color associated with a portion of the clamp that is configured and adapted to facilitate identification of the gender of a baby while the clamp remains on the baby, and a locking portion for securing the arms together when the clamp is closed on the baby's umbilical cord. Methods of identifying the baby's gender, the baby, and inhibiting unauthorized removal of a baby, are also included.

6. Merritt teaches an umbilical cord clamp that contains a unique identification mark, which can include a serial code, bar code, color code, or letter combination. Each of Merritt's clamps must have a different distinctive mark on it. Merritt teaches to use the unique code to prevent unauthorized removal of a newborn from a pre-defined area. Merritt does not teach anything about identifying groups of children, or a gender-identifying means, or a gender-identifying color, or identifying the gender of a child. Rather, Merritt teaches only that a unique code of some sort is applied to the clamp to minimize child abductions from a pre-defined secured area, e.g., a post-natal ward. Also, Merritt does not address gender assurance from the baby's extraction from the mother through and beyond hospital discharge.

7. Dorsey teaches a decorative pair of blue, pink, green, or yellow-handled scissors labeled with birth-data and used to cut an umbilical cord, which are then whisked away to be cleaned, packaged, and presented to the baby's parents as a novelty gimmick. Dorsey does not suggest that the scissors should remain with the newborn, much

less in association with the umbilical cord, but instead teaches that the scissors are immediately removed from the baby's vicinity and separately packaged and provided in a nice display for the parents. Dorsey also does not teach to keep the presently recited gender-identifying color with the baby, or even to use its colors to identify the gender of the baby to facilitate gender-identification of the baby. Instead, Dorsey is simply a reminder to the parent's friends and relatives that they have a child of a particular gender, rather than providing a gender-identification means or color to or on the baby. Also, Dorsey does not teach that its colored scissors are actually attached to the baby, nor would they because Dorsey teaches to immediately clean the scissors after cutting the cord.

8. Merritt and Dorsey do not provide any motivation to take the typically blue or pink handle color of the Dorsey scissors, which are immediately removed from the baby's presence for cleaning and packaging, and the unique code or other identifier of Dorsey that is on an umbilical cord clamp to prevent unauthorized removal of the baby from a pre-set area. Actually, there would have been no reason to select the concept of colored-handles on the novelty scissors that are taken away from the child and combining them with the security devices of Merritt, because the Dorsey scissors were never meant to identify the baby's gender on the spot. Moreover, Dorsey teaches two main classes of colors, while Merritt teaches exactly the opposite—that unique selections of color codes or other unique indicia can be included on a clamp. Even when considering all their teachings together, Merritt and Dorsey still fail to teach putting a gender-identifying means on a baby or of identifying the baby's gender. Thus, they cannot teach my invention recited in claims 17-25.

9. On the contrary, the lack of a reliable, essentially error-free manner of determining the gender of a newborn baby without repeated undressing the baby has been a longstanding problem in the obstetric field. As of now, there are often embarrassing errors in misidentifying the gender of a baby for health care workers, parents, and visitors to the post-natal wards. In particular, many parents tend to be uptight, annoyed, or confused when their precious daughter is improperly categorized as a "he" and vice versa. One common solution for this problem prior to the invention, which is still typically in use today, involves use of blue or pink baby hats or other clothing. Unfortunately, many types of clothing such as hats tend to easily fall off of babies, and tend to be applied improperly when tired health care providers re-apply the hat or other colored clothing to a baby. Thus, not only do such hats or

clothing not always remain with the child, but the wrong color may be applied to the child at various times causing temporary confusion.

10. To the best of my knowledge, there has been no solution even to the present time of this problem of misidentifying the gender of newborn children while they are clothed. Most newborns in hospitals are still typically found wearing a diaper or a generic hospital shirt or jacket, which makes repeated and accurate gender-identification a problem. Based on my experience delivering children, the invention of Dorsey, or the alleged combination of Merritt and Dorsey, has not been adopted by anyone in the field. Thus, a solution was and is still required, which the surprising and unexpected invention presently recited in claims 17-25 solves.

11. The present invention elegantly solves this longstanding problem in the art by applying a gender-identifying clamp to a nude newborn at birth--when the chance for gender misidentification is significantly lower than later times when clothes are worn and gender errors are made. The clamp of the invention remains with the diapered-newborn baby until the umbilical cord stump falls off, which is generally after the baby departs from the hospital or other pre-defined area and typically takes about 1-2 weeks after birth. Thus, the clamp reduces risk and saves cost while improving patient, i.e., the mother's, satisfaction. The inventive clamp will permit immediate and error-free gender-identification of babies even when a diaper or some clothing is being worn, and unlike Merritt and Dorsey, solves the long-standing in-patient problem of newborn gender identification.

12. Thus, it is my opinion and judgment, as one of ordinary skill in the art, there was and is no motivation to use Merritt's uniquely-coded umbilical cord clamps for gender-identifying means even in view of Dorsey's gender-colored novelty scissors. It would also not have been reasonably expected that colors from gender-colored scissors should be added to the security-coded clamps of Merritt to provide the different and surprising benefits of my claimed umbilical cord clamps and methods. Thus, the claimed invention provides a surprising advance that has been absent in the art and clinical medical practice management of a newborn, even when considering a combination of Merritt and Dorsey. Moreover, it is my opinion and judgment, as one of ordinary skill in the art, that the invention of claims 17-25 provides a simple solution to the longstanding problem of gender-misidentification among newborns, which problem no one else has yet been able to adequately solve.

13. I further declare that all statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Dated: 02/10/05

George H. Small, M.D., M.P.H.
George H. Small, M.D., M.P.H.